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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference P 02 127 WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/DK 02/00624	International filing date (day/month/year) 24.09.2002	Priority date (day/month/year) 24.09.2002
International Patent Classification (IPC) or both national classification and IPC A23G3/30		
Applicant GUMLINK AS et al.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of 10 sheets.

- This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 08.03.2004	Date of completion of this report 23.11.2004
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**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/DK 02/00624

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-22 as originally filed

Claims, Pages

1-55 received on 08.11.2004 with letter of 04.11.2004

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/DK 02/00624**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-55
	No: Claims	
Inventive step (IS)	Yes: Claims	1-55
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-55
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/DK 02/00624

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: EP-A-0 711 506 (UNIV GRONINGEN) 15 May 1996 (1996-05-15)

Novelty:

Document D1, which is considered to represent the most relevant state of the art, discloses chewing gum from which the subject-matter of claim 1 differs in that a water content less than about 2% by weight in chewing gum is not directly and unambiguously derivable from D1.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

Inventive Step:

The problem to be solved by the present invention may be regarded as providing a chewing gum composition comprising biodegradable polymers which may be hydrolytically degraded prior to chewing as a result of water being present in a too large amount inside the chewing gum.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons: The specific water amount in a chewing gum claimed in the present invention has not been taught in D1.

There is no hint in D1 for a skilled person to choose the selected water amount in order to solve the presently posed problem.

The conventional chewing gum components (e.g. softeners such as sorbitol, glycerin, sugar syrup) indicated in D1 are typically water-containing components.

REPLACED BY
ART 34 AMDT

Patent Claims

1. Chewing gum comprising at least one biodegradable polymer and chewing gum ingredients,
5 said chewing gum ingredients being chosen from the groups of softeners, sweeteners, flavoring agents, active ingredients, fillers, mixtures thereof and
said chewing gum containing less than about 2.0 weight percent water of the
10 chewing gum
2. Chewing gum according to claim 1, wherein said chewing gum containing from about 0.01 to about 2.0 weight percent water of the chewing gum
- 15 3. Chewing gum according to claim 1 or 2, wherein said chewing gum containing less than 1.0 weight percent water of the chewing gum
4. Chewing gum according to claim any of the claims 1-3, wherein said chewing gum containing less than 0.75 weight percent water of the chewing gum
20
5. Chewing gum according to claim any of the claims 1-4, wherein said chewing gum containing less than 0.2 weight percent water of the chewing gum
6. Chewing gum according to claim any of the claims 1-5,
25 wherein the at least one biodegradable polymer is a polyester polymer obtained by the polymerization of one or more cyclic esters by ring-opening and where at least one of the cyclic esters are selected from the groups of glycolides, lactides, lactones, cyclic carbonates or mixtures thereof.
- 30 7. Chewing gum according to claim any of the claims 1-6,
wherein the at least one biodegradable polymer is a polyester copolymer obtained by the polymerization of two or more cyclic esters by ring-opening and where at least

one of the cyclic esters are selected from the groups of glycolides, lactides, lactones, cyclic carbonates or mixtures thereof.

8. Chewing gum according to claim any of the claims 1-7,
5 wherein the rheological properties of the degradable polymer is controlled by adjusting the functional number of initiator.
9. Chewing gum according to claim any of the claims 1-8,
wherein the lactone monomers are chosen from the group of ϵ -caprolactone, δ -
10 valerolactone, γ -butyrolactone, and β -propiolactone. It also includes ϵ -caprolactones, δ -valerolactones, γ -butyrolactones, or β -propiolactones that have been substituted with one or more alkyl or aryl substituents at any non-carbonyl carbon atoms along the ring, including compounds in which two substituents are contained on the same carbon atom and mixtures thereof.
- 15 10. Chewing gum according to claim any of the claims 1-9,
wherein the carbonate monomer is selected from the group of trimethylene carbonate, 5-alkyl-1,3-dioxan-2-one, 5,5-dialkyl-1,3-dioxan-2-one, or 5-alkyl-5-alkyloxycarbonyl-1,3-dioxan-2-one, ethylene carbonate, 3-ethyl-3-hydroxymethyl,
20 propylene carbonate, trimethylolpropane monocarbonate, 4, 6dimethyl-1, 3-propylene carbonate, 2, 2-dimethyl trimethylene carbonate, and 1, 3-dioxepan-2-one and mixtures thereof.
11. Chewing gum according to claim any of the claims 1-10,
25 wherein the chewing gum is substantially free of water containing sweeteners or softeners.
12. Chewing gum according to claim any of the claims 1-11,
wherein the chewing gum comprises at least one low hygroscopic softener or
30 sweetener.
13. Chewing gum according to claim any of the claims 1-12,

wherein the at least one low hygroscopic softeners or chewing gum comprises powdered erithritol.

14. Chewing gum according to any of claims 1- 13, wherein
5 said chewing gum ingredients comprise flavoring agents.

15. Chewing gum according to any of claims 1- 14, wherein
said flavoring agents comprises natural and synthetic flavorings in the form of
natural vegetable components, essential oils, essences, extracts, powders, including
10 acids and other substances capable of affecting the taste profile

16. Chewing gum according to any of claims 1-15, wherein
said chewing gum comprises flavor in an amount of 0.01 to about 30 wt %, said
percentage being based on the total weight of the chewing gum
15

17. Chewing gum according to any of claims 1-16, wherein
said chewing gum comprises flavor in an amount of 0.2 to about 4 wt %, said
percentage being based on the total weight of the chewing gum

20 18. Chewing gum according to any of claims 1- 17, wherein
said flavor comprises water soluble ingredients.

19. Chewing gum according to any of claims 1-18, wherein
said water soluble flavor comprises acids.

25

20. Chewing gum according to any of claims 1-19, wherein
said flavor comprises water insoluble ingredients.

21. Chewing gum according to any of claims 1- 20, wherein
30 said chewing gum ingredients comprising sweeteners.

22. Chewing gum according to any of claims 1-21,

wherein said sweetener comprises bulk sweeteners

23. Chewing gum according to any of claims 1-22,
wherein the chewing gum comprises bulk sweeteners in the amount of about 5 to
5 about 95% by weight of the chewing gum, more typically about 20 to about 80% by
weight of the chewing gum.

24. Chewing gum according to any of claims 1-23, wherein said sweetener comprises
high intensity sweeteners

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25. Chewing gum according to any of claims 1-24, wherein the high intensity
sweeteners comprises sucralose, aspartame, salts of acesulfame, alitame, saccharin
and its salts, cyclamic acid and its salts, glycyrrhizin, dihydrochalcones, thaumatin,
monellin, sterioside, alone or in combination

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26. Chewing gum according to any of claims 1-25,
wherein the chewing gum comprises high intensity sweeteners in an amount of about
0 to about 1% by weight of the chewing gum, more typically about 0.05 to about 0.5
% by weight of the chewing gum.

20

27. Chewing gum according to any of claims 1- 26,
wherein the chewing gum comprises at least one softener.

28. Chewing gum according to any of claims 1- 27,
25 wherein the at least one softener comprises tallow, hydrogenated tallow,
hydrogenated and partially hydrogenated vegetable oils, cocoa butter, glycerol
monostearate, glycerol triacetate, lecithin, mono-, di- and triglycerides, acetylated
monoglycerides, fatty acids - such as stearic, palmitic, oleic and linoleic acids,
waxes, PGE and mixtures thereof.

30

29. Chewing gum according to any of claims 1- 28,

wherein the chewing gum comprises softeners in the amount of about 0 to about 18% by weight of the chewing gum, more typically about 0 to about 12 % by weight of the chewing gum.

- 5 30. Chewing gum according to any of claims 1- 29, wherein said chewing gum ingredients comprise active ingredients.
31. Chewing gum according to any of claims 1- 30, said active ingredients being selected from the group of: Acetaminophen, Acetylsalicylsyre Buprenorphine
- 10 Bromhexin Celcoxib Codeine, Diphenhydramin, Diclofenac, Etoricoxib, Ibuprofen, Indometacin, Ketoprofen, Lumiracoxib, Morphine, Naproxen, Oxycodon, Parecoxib, Piroxicam, Pseudoefedrin, Rofecoxib, Tenoxicam, Tramadol, Valdecocib, Calciumcarbonat, Magaldrate, Disulfiram, Bupropion, Nicotine, Azithromycin, Clarithromycin, Clotrimazole, Erythromycin, Tetracycline, Granisetron,
- 15 Ondansetron, Prometazin, Tropisetron, Brompheniramine, Ceterizin, Ieco-Ceterizin, Chlorcyclizine, Chlorpheniramin, Chlorpheniramin, Difenhydramine, Doxylamine, Fenofenadin, Guaifenesin, Loratidin, des-Loratidin, Phenyltoloxamine, Promethazin, Pyridamine, Terfenadin, Troxerutin, Methyldopa, Methylphenidate, Benzalcon. Chloride, Benzeth. Chloride, Cetylpyrid. Chloride, Chlorhexidine, Ecabet-sodium,
- 20 Haloperidol, Allopurinol, Colchicine, Theophylline, Propanolol, Prednisolone, Prednisone, Fluoride, Urea, Miconazole, Actot, Glibenclamide, Glipizide, Metformin, Miglitol, Repaglinide, Rosiglitazone, Apomorfin, Cialis, Sildenafil, Vardenafil, Diphenoxylate, Simethicone, Cimetidine, Famotidine, Ranitidine, Ratinidine, cetizin, Loratadine, Aspirin, Benzocaine, Dextrometorphan, Ephedrine,
- 25 Phenylpropanolamine, Pseudoephedrine, Cisapride, Domperidone, Metoclopramide, Acyclovir, Dioctylsulfosucc., Phenolphthalein, Almotriptan, Eletriptan, Ergotamine, Migea, Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan, Aluminium salts, Calcium salts, Ferro salts, Silver salts, Zinc-salte, Amphotericin B, Chlorhexidine, Miconazole, Triamcinolonacetonid, Melatonine, Phenobarbitol, Caffeine,
- 30 Benzodiazepiner, Hydroxyzine, Meprobamate, Phenothiazine, Buclizine, Brometazine, Cinnarizine, Cyclizine, Difenhydramine, Dimenhydrinate, Buflomedil, Amphetamine, Caffeine, Ephedrine, Orlistat, Phenylephedrine, Phenylpropanolamin,

Pseudoephedrine, Sibutramin, Ketoconazole, Nitroglycerin, Nystatin, Progesterone, Testosterone, Vitamin B12, Vitamin C, Vitamin A, Vitamin D, Vitamin E, Pilocarpin, Aluminiumaminoacetat, Cimetidine, Esomeprazole, Famotidine, Lansoprazole, Magnesiumoxide, Nizatide and/or Ratinidine or derivates and
5 mixtures thereof.

32. Chewing gum according to any of claims 1-31, wherein the chewing gum is substantially free of non-biodegradable polymers

10 33. Chewing gum according to any of claims 1-32, wherein the at least two or more cyclic esters are selected from the groups of glycolides, lactides, lactones, cyclic carbonates or mixtures thereof.

34. Chewing gum according to any of claims 1-33, wherein lactone monomers are
15 chosen from the group of ϵ -caprolactone, δ -valerolactone, γ -butyrolactone, and β -propiolactone. It also includes ϵ -caprolactones, δ -valerolactones, γ -butyrolactones, or β -propiolactones that have been substituted with one or more alkyl or aryl substituents at any non-carbonyl carbon atoms along the ring, including compounds in which two substituents are contained on the same carbon atom.

20 35. Chewing gum according to any of claims 1-34, wherein the carbonate monomer is selected from the group of trimethylene carbonate, 5-alkyl-1,3-dioxan-2-one, 5,5-dialkyl-1,3-dioxan-2-one, or 5-alkyl-5-alkyloxycarbonyl-1,3-dioxan-2-one, ethylene carbonate, 3-ethyl-3-hydroxymethyl,
25 propylene carbonate, trimethylolpropane monocarbonate, 4, 6dimethyl-1, 3-propylene carbonate, 2, 2-dimethyl trimethylene carbonate, and 1, 3-dioxepan-2-one and mixtures thereof.

30 36. Chewing gum according to any of claims 1- 35, wherein cyclic ester polymers and their copolymers resulting from the polymerization of cyclic ester monomers include, but are not limited to : poly (L-

lactide) ; poly (D-lactide) ; poly (D, L-lactide) ; poly (mesolactide) ; poly (glycolide)
; poly (trimethylenecarbonate) ; poly (epsilon-caprolactone) ;
poly (L-lactide-co-D, L-lactide) ; poly (L-lactide-co-meso-lactide) ; poly (L-lactide
co-glycolide) ; poly (L-lactide-co-trimethylenecarbonate) ; poly (L-lactide
5 co-epsilon-caprolactone) ; poly (D, L-lactide-co-meso-lactide) ; poly (D, L
lactide-co-glycolide) ; poly (D, L-lactide-co-trimethylenecarbonate) ;
poly (D, L-lactide-co-epsilon-caprolactone) ; poly (meso-lactide-co
glycolide) ; poly (meso-lactide-co-trimethylenecarbonate) ; poly (meso
lactide-co-epsilon-caprolactone) ; poly (glycolide-cotrimethylenecarbonate) ; poly
10 (glycolide-co-epsilon-caprolactone).

37. Chewing gum according to any of claims 1-36,
wherein the chewing gum comprises filler.

15 38. Chewing gum according to any of claims 1- 37,
wherein the chewing gum comprises filler in an amount of about 0 to about 50% by
weight of the chewing gum, more typically about 10 to about 40 % by weight of the
chewing gum.

20 39. Chewing gum according to any of claims 1-38,
wherein the chewing gum comprises at least one coloring agent..

40. Chewing gum according to any of claims 1-39, where the chewing gum is coated
with an outer coating.

25 41. Chewing gum according to any of claims 1-40, wherein the outer coating is a
hard coating.

42. Chewing gum according to any of claims 1-41, wherein the hard coating is a
30 coating selected from the group consisting of a sugar coating and a sugarless coating
and a combination thereof.

43. Chewing gum according to any of claims 1-42, wherein the hard coating comprises 50 to 100% by weight of a polyol selected from the group consisting of sorbitol, maltitol, mannitol, xylitol, erythritol, lactitol and isomalt.

5 44. Chewing gum according to any of claims 1-43, wherein the outer coating is an edible film comprising at least one component selected from the group consisting of an edible film-forming agent and a wax.

45. Chewing gum according to any of claims 1-44, wherein the film-forming agent is
10 selected from the group consisting of a cellulose derivative, a modified starch, a dextrin, gelatine, shellac, gum arabic, zein, a vegetable gum, a synthetic polymer and any combination thereof.

46. Chewing gum according to any of claims 1-45, wherein the outer coating
15 comprises at least one additive component selected from the group consisting of a binding agent, a moisture absorbing component, a film forming agent, a dispersing agent, an antisticking component, a bulking agent, a flavouring agent, a colouring agent, a pharmaceutically or cosmetically active component, a lipid component, a wax component, a sugar, an acid and an agent capable of accelerating the after-
20 chewing degradation of the degradable polymer.

47. Chewing gum according to any of claims 1-46, wherein the outer coating is a soft coating.

25 48. Chewing gum according to any of claims 1-47, wherein the soft coating comprises a sugar free coating agent.

49. Chewing gum according to any of claims 1-48,
wherein said chewing gum comprises conventional chewing gum polymers or resins.

30

50. Chewing gum according to any of claims 1-49,

wherein the at least one biodegradable polymer comprises at least 5% of the chewing gum polymers.

51. Chewing gum according to any of claims 1-50,
5 wherein all the biodegradable polymers comprised in the chewing gum comprises at least 25%, preferably at least 50% of the chewing gum polymers.

52. Chewing gum according to any of claims 1-51,
wherein all the biodegradable polymers comprised in the chewing gum comprises at
10 least 80%, preferably at least 90% of the chewing gum polymers.

53. Chewing gum according to any of claims 1-52,
wherein said chewing gum comprises
- said at least one biodegradable polyester copolymer forming a plasticizer of the
15 chewing gum and
- at least one non-biodegradable conventional elastomer.

54. Chewing gum according to any of claims 1-53,
wherein said chewing gum comprises
20 - said at least one biodegradable polyester copolymer forming an elastomer of the chewing gum and
- at least one non-biodegradable conventional natural or synthetic resin.

55. Chewing gum according to any of the claims 1-54, wherein said chewing gum
25 comprises

at least one biodegradable elastomer in the amount of about 0.5 to about 70% wt of the chewing gum,

30 at least one biodegradable plasticizer in the amount of about 0.5 to about 70% wt of the chewing gum and

at least one chewing gum ingredient chosen from the groups of softeners, sweeteners, flavoring agents, active ingredients and fillers in the amount of about 2 to about 80% wt of the chewing gum.

- 5 56. Gum base according to any of claims 1-55.